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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,344	07/08/2003	Linda D. Artman	085747-0245	7848

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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT PAPER NUMBER

1617

DATE MAILED: 12/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/614,344	Applicant(s) ARTMAN ET AL.	
	Examiner Shahnam Sharareh	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37 and 39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37, 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Amendment filed on September 29, 2005 has been entered. Claims 37 and 39 are pending. Any rejection that is not addressed in this Office Action is considered moot in view of a new ground of rejection.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Balandrin et al in view of Drug facts and comparisons 1999 ed. pages 1595-1597("Drug Facts").

Balandrin's teachings are extensively discussed on record. Balandring teaches that isovaleramide is an effective anxiolytic agent and has potential use in treating muscle spasm. Balandrin does not teach the use of isovaleramide for the type of seizures that are enumerated in the instant claim 39.

Drug Facts describes that Diazepam to be indicated for use for treating anxiety disorders and relief of symptoms of anxiety, as well as, treating skeletal muscle spasms, and status epilepticus. (see page 1596-1597). Drug Facts is merely used to show that for the purposes of treating the conditions of anxiety disorders, muscle spasms and convulsive disorders such as status epilepticus, one of ordinary skill in the art would have viewed said conditions to be art equivalents. Thus, one of ordinary skill in the art would have expected to see therapeutic benefits for treating all such conditions, when any agent is found to be effective to treat any one of said conditions.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to employ isovaleramide for convulsive disorders such as status epilepticus, because isovaleramide is an effective antianxiety agent and, as shown by Drug Facts, anxiety disorders, skeletal muscle spasms, and status epilepticus, are art equivalent conditions. One of ordinary skill in the art would have had a reasonable expectation of success in treating status epilepticus with isovaleramide, because other muscle relaxants and antianxiety agents such as diazepam, have been used to treat status epilepticus as well.

3. Claim 39 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Balandrin et al in view of Pharmacotherapy, A Pathophysiologic Approach, (Dipiro et al. 2nd ed. Elsevier, 1991, pages 1232, 1238) ("Pharmacotherapy").

Applicant's arguments with respect to claim 30 have been fully considered but they are not persuasive.

Balandrin teaches Isovaleramide as an anxiolytic agent in patients in need thereof. Balandrin at col 7 specifically states that isovaleramide is useful for treating patients with tension, restlessness and even those suffering from premenstrual syndrome:

Thus, isovaleramide is useful in treating persons suffering from symptoms of mild anxiety, including tension, restlessness, nervousness, inability concentrate, over-aggressiveness, irritability, and insomnia. Other conditions and therapeutic regimens which may benefit from the anxiolytic effects of isovaleramide include the treatment of the symptoms of smoking cessation, treatment of alcoholism and other substance abuse, premenstrual syndrome, menstrual discomfort, and hyperexcitability in children.

Balandrin does not specifically recites the use of isovaleramide for treating headaches. However, headache is almost a symptom for all such conditions.

For example, Pharmacotherapy is merely used to indicate that headache is a common symptom associated with premenstrual syndrome (see table 72.1, 2nd col). Pharmacotherapy also states that antianxiety agents, such as alprazolam, are effective in treating PMS symptoms. (See for example page 1238, 2nd para.).

Thus, even though Balandrin does not specifically teach methods of treating headaches with isovaleramide, it would have been obvious to one of ordinary skill in the art at the time of invention to employ anxiolytic does of isovleramide, as described by Balandrin, for treating symptoms of tension, inability to concentrate, nervousness, and PMS, including heacahes, in patients suffering from such condition. One of ordinary skill in the art at the time of invention would have had a reasonable expectation of success in treating headache with isovelramide, because anxiolytic agents have been shown to at least be effective in treating PMS symptoms which include headaches.

Conclusion

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

Art Unit: 1617

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SREENIVASAN PADMANABHAN
SUPERVISOR, EXAMINER

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